REMARKS

Claims 1, 3, 4, 6, 7, 9, and 15-19 stand rejected under 35 U.S.C. 103(a) for purportedly being unpatentable over Richardson in view of Gordon et al. In view of the amendments to the claims and the following remarks, Applicants request that the Examiner reconsider and withdraw the rejection.

Applicants note that prior to this invention there has not been any medicament or method for preventing the development and progression of a prion disease. Applicants have discovered that essential amino acids selected from the group of isoleucine, leucine, valine and mixtures thereof in an amount of 5-15g/kg body weight is sufficient to suppress the proliferation of prion proteins, and as such, such amount prevents the development of prion diseases. One of skill in the art would be surprised by Applicants' discovery, as prior to this invention, there has never been a medicament or method to prevent prion disease progression.

Applicants note that Richardson teaches a method for remitting or attenuating abnormal movements by administering a meal enriched for large neutral amino acids and teaches that the total amount of valine, isoleucine and leucine to be administered is about 50-1500mg/kg body weight and suggests a starting dose of "150 to 275 mg/kg per day." Richardson's premise is that the levels of phenylalanine accumulated in the plasma and tissues of psychiatric patients play a role in whether such a patient will develop abnormal movement disorders and that patients with tardive dyskinesia may be experiencing small, bur regular relatively higher elevations in plasma phenylalanine (see page 15, lines 20-30). Thus Richardson does not expressly teach that the amino acids being administered would have any effect on prion proliferation, nor does Richardson alone or in combination with Gordon suggest that the amount of amino acids that Richardson administered would inherently have such an effect. The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or

characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (Court reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art). The mere fact that a certain thing may result from a given set of circumstances is not sufficient to establish inherency. See *Cont'l Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1269 (Fed. Cir. 1991) (quoting *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981)); see also *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295 (Fed. Cir. 2002).

The Examiner states that "the discovery of a previously unappreciated property of a prior art composition or of a scientific explanation for the prior art's functioning does not render the old composition patentably new to the discoverer"(Office Action page 6) However, when one, such as Applicants, discovers a previously unknown or unappreciated property of a material and based on that newly discovered property develops a composition and method to treat a previously untreatable disease, Applicants submit the invention is patentable new. To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is <u>necessarily</u> present in the thing described in the reference, and that it <u>would be so recognized</u> by persons of ordinary skill." *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted)(emphasis added) (The claims were drawn to a disposable diaper having three fastening elements. The reference disclosed two fastening elements that could perform the same function as the three fastening elements in the claims. The court construed the claims to require three separate elements and held that the reference did not disclose a separate third fastening element, either expressly or inherently.)

In the present case no one, prior to Applicants' invention, knew that valine, leucine and isoleucine could potentially suppress prion proliferation. And, one of skill in the art in view of Richardson's teachings that the effect of the amino acids was on plasma phenylalanine balance would have no reason to

expect that valine, leucine and isoleucine could be administered in an amount sufficient to suppress prion proliferation and prevent prion disease development. Thus as set forth by *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) the missing descriptive matter, i.e., valine, leucine and isoleucine suppression of prion proliferation, is not necessarily present in the method described in Richardson, and the effect of the amino acids on prion proliferation would <u>not</u> be so recognized by persons of ordinary skill. As such, Applicants' claimed invention is not rendered obvious by the combination of Richardson and Gordon.

In view of the foregoing amendments and remarks, Applicants request that the Examiner reconsider and withdraw the rejection of the claims under 35 U.S.C. 103(a) over Richardson in view of Gordon.

If there are any questions regarding this response or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket # 101551.55779US).

Respectfully submitted,

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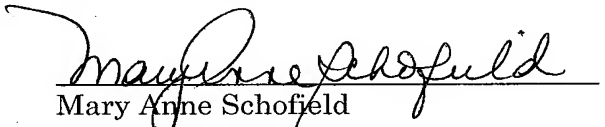

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